

State of Wisconsin



2003 Assembly Bill 845

Date of enactment: April 6, 2004
Date of publication*: April 20, 2004

2003 WISCONSIN ACT 175

AN ACT *to create* 255.055 of the statutes; **relating to:** establishing a cancer drug repository program and requiring the exercise of rule-making authority.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 255.055 of the statutes is created to read:
255.055 Cancer drug repository. (1) DEFINITIONS.

In this section:

(a) "Cancer drug" means a prescription drug that is used to treat any of the following:

1. Cancer or side effects of cancer.
2. The side effects of any prescription drug that is used to treat cancer or side effects of cancer.

(b) "Dispense" has the meaning given in s. 450.01 (7).

(c) "Medical facility" has the meaning given in s. 943.145 (1).

(d) "Pharmacist" has the meaning given in s. 450.01 (15).

(e) "Pharmacy" means a pharmacy that is licensed under s. 450.06.

(f) "Practitioner" has the meaning given in s. 450.01 (17).

(g) "Prescription drug" has the meaning given in s. 450.01 (20).

(2) The department shall establish and maintain a cancer drug repository program, under which any person may donate a cancer drug or supplies needed to administer a cancer drug for use by an individual who meets eligi-

bility criteria specified by rule by the department. Donation may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets requirements specified by rule by the department. The medical facility or pharmacy may charge an individual who receives a cancer drug or supplies needed to administer a cancer drug under this subsection a handling fee that may not exceed the amount specified by rule by the department. A medical facility or pharmacy that receives a donated cancer drug or supplies needed to administer a cancer drug under this subsection may distribute the cancer drug or supplies to another eligible medical facility or pharmacy for use under the program under this section.

(3) A cancer drug or supplies needed to administer a cancer drug may be accepted and dispensed under the program specified in sub. (2) only if all of the following requirements are met:

(a) The cancer drug or supplies needed to administer a cancer drug is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened.

(b) The cancer drug bears an expiration date that is later than 6 months after the date that the drug was donated.

(c) The cancer drug or supplies needed to administer a cancer drug is not adulterated or misbranded, as deter-

* Section 991.11, WISCONSIN STATUTES 2001-02 : Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication as designated" by the secretary of state [the date of publication may not be more than 10 working days after the date of enactment].

mined by a pharmacist employed by, or under contract with, the medical facility or pharmacy, who shall inspect the drug or supplies needed to administer a cancer drug before the drug or supplies are dispensed.

(d) The cancer drug or supplies needed to administer a cancer drug are prescribed by a practitioner for use by an eligible individual and are dispensed by a pharmacist.

(4) No cancer drug or supplies needed to administer a cancer drug that are donated for use under this section may be resold.

(5) Nothing in this section requires that a medical facility, pharmacy, pharmacist, or practitioner participate in the program under this section.

(6) (a) Unless the manufacturer of a drug or supply exercises bad faith, the manufacturer is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a cancer drug or supply manufactured by the manufacturer that is donated by any person under this section, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated cancer drug or supply.

(b) Except as provided in par. (c), any person, except the manufacturer of a drug or supply, is immune from civil liability for injury to or the death of the individual to whom the cancer drug or supply is dispensed and may not be found guilty of unprofessional conduct for his or her acts or omissions related to donating, accepting, distributing, or dispensing a cancer drug or supply under this section.

(c) The immunity or the prohibition on a finding of guilty of unprofessional conduct under par. (b) does not extend to donation, acceptance, distribution, or dispensation of a cancer drug by a person whose act or omission involves reckless, wanton, or intentional misconduct.

(7) The department shall promulgate all of the following as rules:

(a) Requirements for medical facilities and pharmacies to accept and dispense donated cancer drugs or supplies needed to administer cancer drugs under this section, including all of the following:

1. Eligibility criteria.
2. Standards and procedures for accepting, safely storing, and dispensing donated cancer drugs or supplies needed to administer cancer drugs.
3. Standards and procedures for inspecting donated cancer drugs or supplies needed to administer cancer drugs to determine if the cancer drug or supplies needed to administer a cancer drug are in its original, unopened, sealed, and tamper-evident unit dose packaging or, if

packaged in single-unit doses, the single-unit-dose packaging is unopened.

4. Standards and procedures for inspecting donated cancer drugs or supplies needed to administer cancer drugs to determine that the cancer drug or supplies needed to administer a cancer drug are not adulterated or misbranded.

(b) Eligibility criteria for individuals to receive donated cancer drugs or supplies needed to administer cancer drugs dispensed under the program. The standards shall prioritize dispensation to individuals who are uninsured or indigent, but will permit dispensation to others if an uninsured or indigent individual is unavailable.

(c) A means, such as an identification card, by which an individual who is eligible to receive a donated cancer drug or supplies needed to administer a cancer drug may indicate that eligibility.

(d) Necessary forms for administration of the cancer drug repository program, including forms for use by persons that donate, accept, distribute, or dispense cancer drugs or supplies needed to administer cancer drugs under the program.

(e) The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated cancer drugs or supplies needed to administer cancer drugs.

(f) A list of cancer drugs and supplies needed to administer cancer drugs, arranged by category or by individual cancer drug or supply, that the cancer drug repository program will accept for dispensing.

(g) A list of cancer drugs and supplies needed to administer cancer drugs, arranged by category or by individual cancer drug or supply, that the cancer drug repository program will not accept for dispensing. The list shall include a statement that specifies the reason that the cancer drug or supplies needed to administer a cancer drug are ineligible for donation.

SECTION 2. Nonstatutory provisions.

(1) RULES. The department of health and family services shall submit in proposed form the rules required under section 255.055 (7) of the statutes, as created by this act, to the legislative council staff under section 227.15 (1) of the statutes no later than the first day of the 9th month beginning after the effective date of this subsection.

SECTION 3. Effective dates. This act takes effect on the day after publication, except as follows:

(1) The treatment of section 255.055 of the statutes takes effect on July 1, 2005.